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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,051	05/05/2005	Yoshifumi Takenobu	Q87826	8452

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2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
HOUGHTLING, RICHARD A	

ART UNIT	PAPER NUMBER
1617	

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01/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,051	TAKENOBU ET AL.	
	Examiner	Art Unit	
	Richard A. Houghtling, Ph.D.	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12 and 15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05 May 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions, which are not so linked, as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-11 and 15	drawn to method for prevention and/or treatment of spinal canal stenosis, which comprises administering to a mammal in need thereof an effective amount of an aldose reductase inhibitory compound in combination with at least one pharmaceutical agent selected from prostaglandins, prostaglandin derivatives formulations, nonsteroidal anti-inflammatory drugs, vitamin compounds, muscle relaxants, antidepressants, poly ADP-ribose polymerase inhibitors, excitatory amino acid receptor antagonists, radical scavengers, astrocyte modulators, IL-8 receptor antagonists, and immunosuppressive drugs.
Group II, claim 12	drawn to a pharmaceutical composition which comprises an aldose reductase inhibitory compound in combination with at least one pharmaceutical agent selected from prostaglandins, prostaglandin derivatives formulations, nonsteroidal anti- inflammatory drugs, vitamin compounds, muscle relaxants, antidepressants, poly ADP-ribose polymerase inhibitors, excitatory amino acid receptor antagonists, radical scavengers, astrocyte modulators, IL-8 receptor antagonists, and immunosuppressive drugs.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature in all groups is aldose reductase inhibitory compound.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is permitted only if all, inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any). Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," should be considered with respect to novelty and inventive step.

The common technical feature in all groups is aldose reductase inhibitory compound. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art.

In this case, DuBois (U.S. Patent, 6,399,601 see PTO-892) teaches a pharmaceutical composition comprising bicyclic pyrrolyl amides in combination with aldose reductase inhibitors. DuBois teaches aldose reductase inhibitors such as zopolrestat (col. 25, lines 51-63) as well as many others including: ponalrestat, tolrestat, epalrestat, zenarestat, SPR-210 (see col. 26, lines 37-67 to col. 28, lines 1-14).

In the pending application, the two independent claims to a method (claim 1) and a pharmaceutical composition (claim 12) each include an aldose reductase inhibitory compound. Applicants' independent claims both include compounds from the broad genus of aldose reductase inhibitors and not to a specific compound. As many examples of aldose reductase inhibitors are known in the prior art and further are taught by DuBois '601, there is no special technical feature present in the claims. As a result, the inventions in Groups I-II fail to make a contribution over the prior art with respect to novelty and inventive step. In conclusion, there is a lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

Furthermore, the claims encompass methods and pharmaceutical compositions using a broad genus of aldose reductase inhibitors, which include many different

compositions. The compounds vary distinctly in their structures and functions and thus, an individual search is required of each individual compound. Therefore, as part of electing one of the groups as the elected invention, Applicant is also required to elect a specific aldose reductase inhibitor compound, to which the elected invention will be examined on the merits; as well as, identify the claims to which the elected compound is drawn, including any claims subsequently added. This requirement is *not* to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Applicant is further required to make an election of species of the pharmaceutical agent which is to be used in the combination with the specific aldose reductase inhibitor elected above. Claims 12 and 15 encompass a pharmaceutical composition or a method of administering a pharmaceutical composition comprising an aldose reductase inhibitor and at least one pharmaceutical agent, each agent of which is itself, a broad genus and therefore includes many different compositions. The compounds vary distinctly in their structures and functions and thus, an individual search is required of each individual compound within the broad genus of pharmaceutical agent. Therefore, as part of electing one of the groups as the elected invention, Applicant is also required to elect which pharmaceutical agent and further elect a specific compound from the genus of the elected pharmaceutical agent, to which the elected invention will be examined on the merits; as well as, identify the claims to which the elected compound is

drawn, including any claims subsequently added. This requirement is *not* to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.141).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard A. Houghtling, Ph.D. whose telephone number is 571-272-9334. The examiner can normally be reached Monday to Thursday from 8:00 am - 5:00 pm, and on alternate Fridays 8:00 AM - 12:00 Noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0623. The Group 1600 fax phone number where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Richard A. Houghtling, Ph.D.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER